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WITNESS my hand this
Sixteenth day of August 2005

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Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

Lumen with seal in a cochlear implant electrode array

The invention is described in the following statement:

Field of the Invention

The present invention relates to an implantable device and, in particular, to an implantable cochlear electrode assembly.

Background of the Invention

Hearing loss, which may be due to many different causes, is generally of two types, conductive and sensorineural. Of these types, conductive hearing loss occurs where the normal mechanical pathways for sound to reach the hair cells in the cochlea are impeded, for example, by damage to the ossicles. Conductive hearing loss may often be helped by use of conventional hearing aid systems, which amplify sound so that acoustic information does reach the cochlea and the hair cells.

In many people who are profoundly deaf, however, the reason for deafness is sensorineural hearing loss. This type of hearing loss is due to the absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are thus unable to derive suitable benefit from conventional hearing aid systems, because there is damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve. US Patent 4532930, the contents of which are incorporated herein by reference, provides a description of one type of traditional cochlear implant system.

Cochlear implant systems have typically consisted of two key components, namely an external component commonly referred to as a processor unit, and an implanted internal component commonly referred to as a receiver/stimulator unit. Traditionally, both of these components have cooperated together to provide the sound sensation to an implantee.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds and particularly speech into a coded signal, a power source such as a battery, and an external antenna transmitter coil.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted receiver/stimulator unit situated within a recess of the temporal bone of the implantee. This transcutaneous transmission occurs through use of an inductive coupling provided between the external antenna transmitter coil which is positioned to communicate with an implanted antenna receiver coil provided with the receiver/stimulator unit. This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted receiver/stimulator unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted receiver/stimulator unit typically includes the antenna receiver coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlea electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

The external componentry of the cochlear implant has been traditionally carried on the body of the implantee, such as in a pocket of the implantee's clothing, a belt pouch or in a harness, while the microphone has been mounted on a clip mounted behind the ear or on a clothing lapel of the implantee.

More recently, due in the main to improvements in technology, the physical dimensions of the speech processor have been able to be reduced allowing for the external componentry to be housed in a small unit capable of being worn behind the ear of the implantee. This unit has allowed the microphone, power unit and the speech processor to be housed in a single unit

capable of being discretely worn behind the ear, with the external transmitter coil still positioned on the side of the user's head to allow for the transmission of the coded sound signal from the speech processor and power to the implanted stimulator unit.

Together with improvements in available technology, much research has been undertaken in the area of understanding the way sound is naturally processed by the human auditory system. With such an increased understanding of how the cochlea naturally processes sounds of varying frequency and magnitude, there is a need to provide an improved cochlear implant system that delivers electrical stimulation to the auditory nerve in a way that takes into account the natural characteristics of the cochlea.

It is known in the art that the cochlea is tonotopically mapped. In other words, the cochlea can be partitioned into regions, with each region being responsive to signals in a particular frequency range. This property of the cochlea is exploited by providing the electrode assembly with an array of electrodes, each electrode being arranged and constructed to deliver a cochlea stimulating signal within a preselected frequency range to the appropriate cochlea region. The electrical currents and electric fields from each electrode stimulate the cilia disposed on the modiolus of the cochlea. Several electrodes may be active simultaneously.

It has been found that in order for these electrodes to be effective, the magnitude of the currents flowing from these electrodes and the intensity of the corresponding electric fields, are a function of the distance between the electrodes and the modiolus. If this distance is relatively great, the threshold current magnitude must be larger than if the distance is relatively small. Moreover, the current from each electrode may flow in all directions, and the electrical fields corresponding to adjacent electrodes may overlap, thereby causing cross-electrode interference. In order to reduce the threshold stimulation amplitude and to eliminate cross-electrode interference, it is advisable to keep the distance between the electrode array and the modiolus as small as possible. This is best accomplished by providing the electrode array in the shape which generally follows the shape of the modiolus. Also, this way of delivering the electrical stimulation to the auditory nerve is most

effective as the electrode contacts are as close as possible to the auditory nerves that are particularly responsive to selected pitches of the sound waves.

In order to achieve this electrode array position close to the inside wall of the cochlea, the electrode needs to be designed in such a way that it assumes this position upon or immediately following insertion into the cochlea. This is a challenge as the array needs to be shaped such that it assumes a curved shape to conform with the shape of the modiolus and must also be shaped such that the insertion process causes minimal trauma to the sensitive structures of the cochlea. In this sense, it has been found to be desirable for the electrode array to be generally straight during the insertion procedure.

Several procedures have been adopted to provide an electrode assembly that is relatively straightforward to insert while adopting a curved configuration following insertion in the cochlea. In one case, a straight platinum wire stylet is positioned within a lumen extending along at least a portion of the length of the assembly. The stylet is relatively stiffer than the body of the assembly and serves to hold a pre-curved electrode array in a generally straight configuration up until insertion. Following insertion, the platinum stylet is withdrawn from the lumen allowing the array to return to its pre-curved configuration.

The presence of any lumen within the electrode assembly for the stylet may pose a potential pathway for pathogens including harmful bacteria, to migrate from a location external the cochlea into the cochlea if there is an opening from the lumen into the cochlea.. While most implants are typically designed and constructed to ensure there is no potential pathway, other circumstances may dictate that such a lumen or an opening from such a lumen is desirable. In this case, the present invention provides a mechanism for preventing any potential migration of pathogens through the assembly.

While the above description of the prior art is directed to cochlear implant electrode assemblies, similar issues of potential pathogen migration arise in other implantable devices using electrode assemblies, such as midbrain implants and muscle stimulation systems used in function electronic stimulation (FES) systems.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed in Australia before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present invention is an implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end and having at least one electrode mounted thereon;

a lumen extending into and along the at least a portion of the elongate member from an orifice positioned at or relatively closer to the proximal end than the distal end, the lumen being adapted to receive a stiffening element through the orifice; and

a seal that is pierceable by the stiffening element but which at least substantially seals the lumen following removal of the stiffening element therefrom.

According to a second aspect, the present invention is an implantable tissue-stimulating device comprising:

a resiliently flexible elongate member having a proximal end and a distal end and having at least one electrode mounted thereon;

a lumen extending into and along the at least a portion of the elongate member from an orifice positioned at or relatively closer to the proximal end than the distal end;

a stiffening element extending through at least a portion of the lumen and out through the orifice; and

a seal that at least substantially seals the lumen following removal of the stiffening element therefrom.

In one embodiment, the seal can be positioned in the lumen at or adjacent the orifice thereof. In one embodiment, the seal can extend over the orifice and be entirely external the lumen. In a still further embodiment, the seal can be positioned at the orifice. In this embodiment, the seal can extend partially outside the orifice and partially inside the orifice. In one embodiment, the seal can be essentially flush or flush with the orifice in the lumen.

In a still further embodiment, the seal can be formed from a resilient material. In this embodiment, the resilience of the seal is preferably sufficient that on removal of the stiffening element therefrom, the seal preferably closes across the passage formed in the seal by the placement of the stiffening element. In one embodiment, a slit can be formed in the seal that facilitates the passage of the stiffening element through the seal. Again, the resilience of the seal is preferably such that the slit is closed on removal of the stiffening element therefrom.

In yet a further embodiment, the seal can be formed of a silicone polymer. In one embodiment, a suitable portion of silicone polymer can be placed over or in the orifice of the lumen. In this embodiment, the drop preferably cures and forms a meniscus-shaped layer over the lumen orifice. In another embodiment, a separately moulded seal can be formed and then adhered to the elongate member over the orifice. In this case, the seal can preferably have a diameter greater than the orifice (eg. a diameter of about or greater than 0.18mm) and a thickness of about 0.2mm.

In a preferred embodiment of this invention, the device is a cochlear implant electrode assembly. In another embodiment, the device is adapted to deliver stimulation to the brain, such as the midbrain. Still further, the device can be adapted to deliver functional electrical stimulation to one or more muscle groups in the body of an implantee.

In a further embodiment, the distal end of the elongate member is adapted to be inserted firstly into the implantee.

The lumen can be circular in cross-section or have any other suitable cross-sectional shape. In one embodiment, the lumen extends through the elongate member for a substantial portion of its length. In a further embodiment, the lumen extends from an opening at the proximal end of the elongate member to a position that is adjacent the distal end thereof.

In a further embodiment, the elongate member can have a plurality of electrodes mounted thereon. In one embodiment, the electrodes can be formed of a biocompatible metallic material, such as platinum.

In a further embodiment, the elongate member can have a first configuration selected to allow said member to be more readily inserted into an implantee's body, such as the cochlea, and a second configuration wherein said elongate member is more readily adapted to apply a preselected tissue stimulation with the electrodes. In a further embodiment, the elongate member can have at least one intermediate configuration between said first and second configurations.

In a still further embodiment, at least a portion of the outer surface of the elongate member can have a coating of lubricious material. In a further embodiment, a substantial portion of the outer surface can have a coating of the lubricious material. In a still further embodiment, the entire outer surface of the elongate member can have a coating of the lubricious material.

The lubricious material preferably becomes lubricious on being brought into contact with a fluid, such as a saline solution. Still further, the coating preferably becomes lubricious on being brought into contact with a body fluid, such as cochlear fluid.

In one embodiment, the lubricious material is selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA). It is envisaged that other similar materials could also be used.

In yet another embodiment, the device can include a stiffening element made of a second material relatively stiffer than the resiliently flexible material of the elongate member. The stiffening element can be adapted to bias the elongate member into the first configuration.

In a preferred embodiment, the second configuration of the elongate member is curved. More preferably, the elongate member adopts a spiral configuration when in the second configuration.

The elongate member is preferably preformed from a plastics material with memory and is preformed to the second configuration.

In a preferred embodiment, the first configuration is preferably substantially straight. More preferably, the first configuration is straight.

In a preferred embodiment, the elongate member is formed from a suitable biocompatible material. In one embodiment, the material can be a silicone, such as Silastic MDX 4-4210. In another embodiment, the elongate member can be formed from a polyurethane or similar material.

In a preferred embodiment, the stiffening element can be formed from a non-bioresorbable material. In this embodiment, the stiffening element can comprise a metallic stylet, or a stylet-like element formed from any other suitable stiffening material, extending through a lumen in the elongate member. In one embodiment, the stylet can be formed from a biocompatible metal, a biocompatible metallic alloy or a biocompatible relatively stiff plastic. In a preferred embodiment, a metal stylet can be formed from platinum.

In the case of a metal stylet, the stylet can extend out of the orifice through the seal allowing the stylet to be manipulated and removed from the lumen during or following insertion of the device.

Once implanted, the electrodes can receive stimulation signals from a stimulator device. The stimulator device is preferably electrically connected to the elongate member by way of an electrical lead. The lead can include the

one or more wires extending from each electrode of the array mounted on the elongate member.

In one embodiment, the lead can extend from the elongate member to a stimulator device or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing of the stimulator device, required to connect the wires extending from the electrodes to the stimulator device. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the necessary electrical connection between the wires extending from the electrodes and the stimulator device.

The stimulator device is preferably positioned within a housing that is implantable within the implantee. The housing for the stimulator device is preferably implantable within the bony well in the bone behind the ear posterior to the mastoid.

When implantable, the housing preferably contains, in addition to the stimulator device, a receiver device. The receiver device is preferably adapted to receive signals from a controller means. The controller means is, in use, preferably mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the implantee.

Signals can preferably travel from the controller means to the receiver device and vice versa. The receiver device can include a receiver coil adapted to receive radio frequency (RF) signals from a corresponding transmitter coil worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver coil, the receiver coil can preferably transmit signals to the transmitter coil which receives the signals.

The transmitter coil is preferably held in position adjacent the implanted location of the receiver coil by way of respective attractive magnets mounted centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the pinna of the implantee, however, other suitable locations can be envisaged, such as a lapel of the implantee's clothing. The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted receiver/stimulator device using the transmitter and receiver coils. The implanted receiver/stimulator device demodulates the FM signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted receiver/stimulator device and the electrode array.

While the implant system can rely on external componentry, in another embodiment, the controller means, including the microphone, speech processor and power supply can also be implantable. In this embodiment, the controller means can be contained within a hermetically sealed housing or the housing used for the stimulator device.

According to a further aspect, the present invention is a method of manufacturing an implantable tissue-stimulating device as defined herein, the method comprising the steps of:

(i) sealing the lumen of the elongate member with a pierceable seal; and

(ii) piercing the seal with a tip of a stiffening element and sliding the stiffening element relatively into the lumen of the elongate member.

According to another aspect, the present invention is a method of manufacturing an implantable tissue-stimulating device as defined herein, the method comprising the steps of:

(i) positioning a stiffening element within a lumen of an elongate member, the stiffening element extending from within the lumen back out through an orifice of the lumen ; and

(ii) sealing the orifice of the lumen of the elongate member with a seal.

According to yet a further aspect, the present invention is a method of placing an implantable tissue-stimulating device as defined herein in the body of an implantee, the method comprising the steps of :

(i) inserting the elongate member into a desired location in the body of the implantee;

(ii) during and/or after insertion, at least partially relatively withdrawing the stiffening element from the lumen through the seal; and

(iii) allowing the seal to at least substantially seal the lumen of the elongate member.

In one embodiment, the stiffening element can be fully withdrawn from the lumen in step (ii). In another embodiment, the stiffening element can be only partially withdrawn from the lumen.

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

Fig. 1 is a pictorial representation of a prior art cochlear implant system;

Fig. 2a is a fragmentary view of a portion of an elongate member having one embodiment of a seal according to the present invention;

Fig. 2b is a fragmentary view of a portion of an elongate member having another embodiment of a seal according to the present invention;

Fig. 3 is a fragmentary view of the elongate member of Fig. 2a with a stylet in position in the elongate member;

Fig. 4a is a perspective view of one embodiment of a seal for use in the invention; and

Fig. 4b is a perspective view of an elongate member depicting the seal of Fig. 4a in position in the orifice of the lumen of the elongate member.

Preferred Mode of Carrying out the Invention

Before describing the features of the present invention, it is appropriate to briefly describe the construction of a typical cochlear implant system with reference to Fig. 1.

Cochlear implants typically consist of two main components, an external component including a speech processor 29, and an internal component including an implanted receiver and stimulator unit 22. The external component includes a microphone 27. The speech processor 29 is, in this illustration, constructed and arranged so that it can fit behind the outer ear 11. Alternative versions may be worn on the body. Attached to the speech processor 29 is a transmitter coil 24 which transmits electrical signals to the implanted unit 22 via a radio frequency (RF) link.

The internal component includes a receiver coil 23 for receiving power and data from the transmitter coil 24. A cable 21 extends from the implanted receiver and stimulator unit 22 to the cochlea 12 and terminates in an electrode array 20. The signals thus received are applied by the array 20 to the basilar membrane 8 and the nerve cells within the cochlea 12 thereby stimulating the auditory nerve 9. The operation of such a device is described, for example, in US Patent No. 4532930.

One embodiment of a cochlear implant electrode assembly according to the present invention is depicted generally as 30 in Figs. 2a and 3. While the drawings are directed to cochlear implants, it will be appreciated that the present invention could be used in conjunction with other implantable tissue-stimulating devices such as devices for delivering stimulation to the brain, such as the midbrain, and devices that can be adapted to deliver functional electrical stimulation to one or more muscle groups in the body of an implantee.

The elongate member 30 has a proximal end 31 and can carry a plurality of electrodes, which are not depicted for reasons of clarity. A lead or cable 21 extends into the elongate member 30. One or more electrically conducting wires 21a (depicted in Fig. 4b) extend through the lead 21 from a stimulator unit to the respective preferably platinum electrodes of the member 30.

The member 30 has a lumen 32 extending into and along at least a portion of the elongate member from an orifice 33. In the depicted embodiment, the lumen 32 is to be understood as extending to a location near the distal end (that is not visible) of the member 30. The distal end is normally the end of the member 30 that is firstly implanted into the implantee. The depicted lumen is circular in cross-section but it will be appreciated that other suitable cross-sectional shapes could be utilised. In a further embodiment, the lumen extends from an opening at the proximal end of the elongate member to a position that is adjacent the distal end thereof.

The lumen 32 is adapted to receive a stiffening element, such as a platinum stylet 34 which is depicted in Fig. 3.

The orifice 33 of the lumen 32 is depicted as being closed by a seal 35 in Figs. 2a and 3. In these Figures, the seal 35 is external to and extends over the orifice 33. In Fig. 2b, an alternative seal structure is depicted as seal 36 in which the seal 36 extends from a position external the orifice into the lumen 32. While not depicted, it will be appreciated that the seal could also be positioned entirely within the lumen 32 of the member. In one embodiment, the seal can be essentially flush or flush with the orifice 33 of the lumen 32.

In these embodiments, the seal is adapted to be positioned at or adjacent the orifice and then be pierceable by the stylet 34 so allowing the stylet 34 to remain in the lumen 32 as long as is required (see Fig. 3). It will be appreciated that the stylet 34 could be positioned in the lumen 32 during the manufacturing process for the member 30. In another embodiment, the stylet may not be inserted into the lumen and so used to straighten the elongate member until a time relatively close to the implantation of the member 30 into the cochlea of an implantee.

In a further embodiment, the stylet 34 can be positioned in the lumen 32 prior to the seal 35 being put in place to close the orifice 33. The result is the same as the alternative method of manufacture with the stylet 34 in the lumen 32 and the orifice sealed by seal 35 as depicted in Fig. 3.

In each depicted embodiment, the seal 35 is formed from a resilient silicone material. In one embodiment, a suitable drop or portion of silicone polymer can be placed over or in the orifice 33 of the lumen 32. In this embodiment, the drop preferably cures and forms a meniscus-shaped layer over the lumen orifice 33. The resilience of the seal 35 is sufficient that on removal of the stylet 34 from the lumen 32, the seal 35 closes across the passage formed in the seal 35 by the placement of the stylet therethrough.

An alternative embodiment of a seal is depicted generally as 40 in Figs. 4a and 4b. In this embodiment, the seal is formed from two separately moulded D-shaped portions that can be positioned side-by-side or overlapping in the orifice 33 of the lumen 32 of the elongate member. The positioning of the portions 41 result in a slit 42 being formed in the seal that facilitates the passage of the stylet through the seal. Again, the resilience of the seal is preferably such that the slit is closed on removal of the stylet therefrom.

In each of the embodiments, the elongate member 30 preferably has a first straight or substantially straight configuration that allows the member 30 to be more readily inserted into an implantee's body, such as the cochlea. The member 30 is, however, preferably pre-formed to preferentially adopt a second spirally-curved configuration when the stylet 34 is not present so that the member 30 is more readily adapted to apply a preselected tissue stimulation with the electrodes.

The elongate member 30 is preferably preformed from a suitable biocompatible material. In one embodiment, the material can be a silicone, such as Silastic MDX 4-4210. In another embodiment, the elongate member can be formed from a polyurethane or similar material.

Once implanted, the electrodes of the member 30 can receive stimulation signals from a stimulator device. The stimulator device is preferably electrically connected to the elongate member by way of the electrical lead 21.

In one embodiment, the lead can extend from the elongate member to a stimulator device or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing of the stimulator device, required to connect the wires extending from the electrodes to the stimulator device. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the necessary electrical connection between the wires extending from the electrodes and the stimulator device.

The stimulator device is preferably positioned within a housing that is implantable within the implantee. The housing for the stimulator device is preferably implantable within the bony well in the bone behind the ear posterior to the mastoid.

When implantable, the housing preferably contains, in addition to the stimulator device, a receiver device. The receiver device is preferably adapted to receive signals from a controller means. The controller means is, in use, preferably mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the implantee.

Signals can preferably travel from the controller means to the receiver device and vice versa. The receiver device can include a receiver coil adapted to receive radio frequency (RF) signals from a corresponding transmitter coil worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver coil, the receiver coil can preferably transmit signals to the transmitter coil which receives the signals.

The transmitter coil is preferably held in position adjacent the implanted location of the receiver coil by way of respective attractive magnets mounted centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is preferably worn on the pinna of the implantee, however, other suitable locations can be envisaged, such as a lapel of the implantee's clothing. The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is transferred to the implanted receiver/stimulator device using the transmitter and receiver coils. The implanted receiver/stimulator device demodulates the FM signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted receiver/stimulator device and the electrode array.

While the implant system can rely on external componentry, in another embodiment, the controller means, including the microphone, speech processor and power supply can also be implantable. In this embodiment, the controller means can be contained within a hermetically sealed housing or the housing used for the stimulator device.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this nineteenth day of December 2002

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

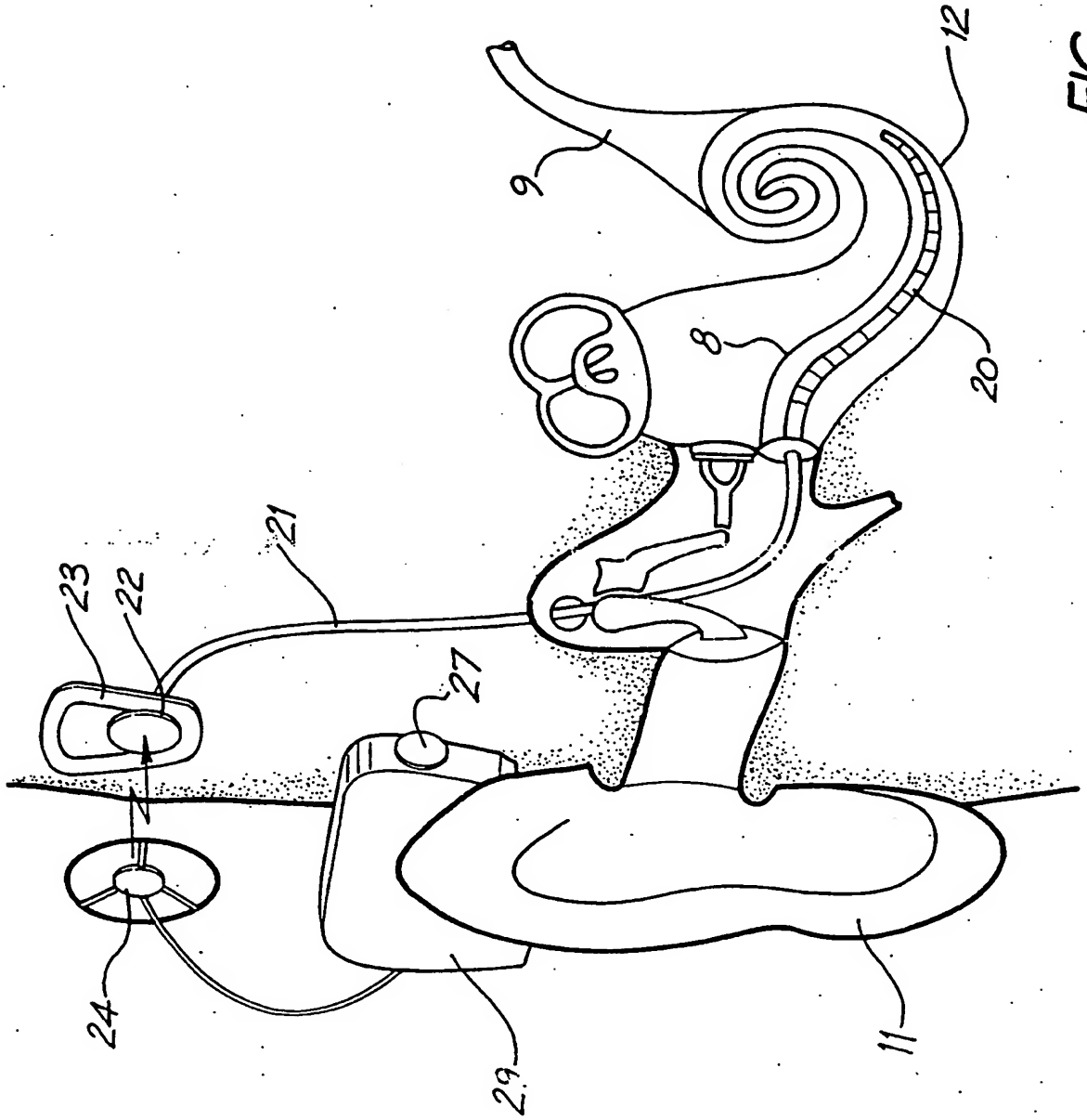


FIG. 1

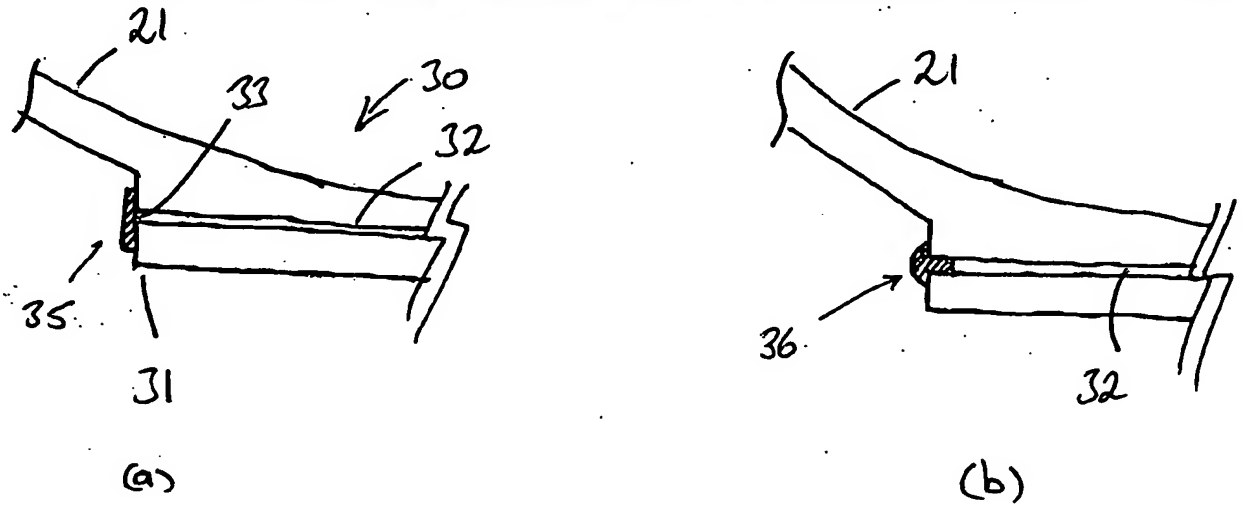


Figure 2

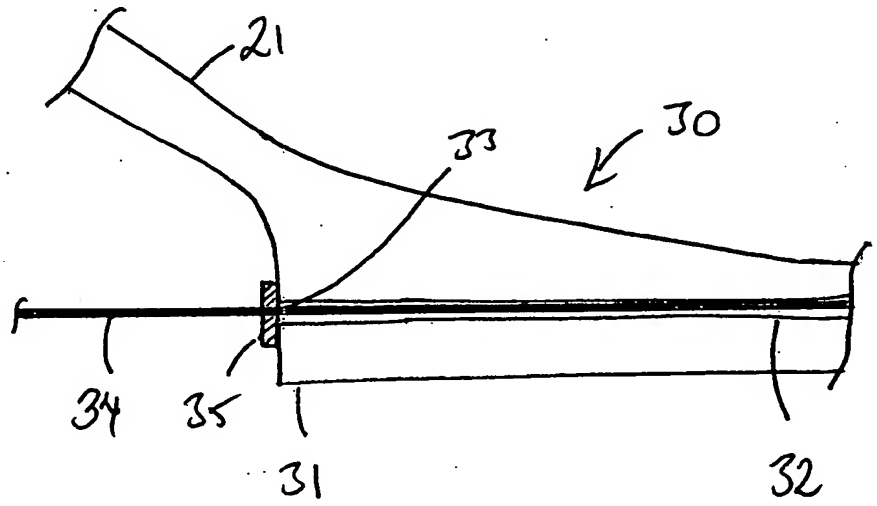
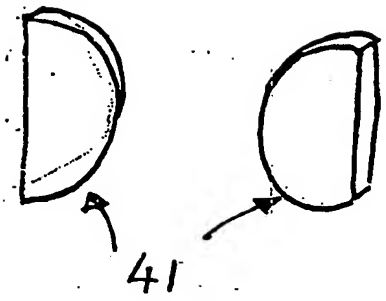


Fig. 3



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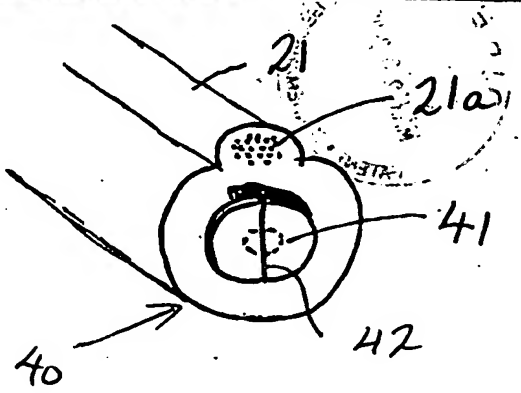

(b)

Figure 4

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